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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

TEVA BRANDED PHARMACEUTICAL
PRODUCTS R&D, INC., NORTON
(WATERFORD) LTD., and TEVA
PHARMACEUTICALS USA, INC.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS OF NEW
YORK, LLC, AMNEAL IRELAND LIMITED,
AMNEAL PHARMACEUTICALS LLC, and
AMNEAL PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 23-cv-20964-SRC-MAH

Electronically Filed

JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Pursuant to Local Patent Rule 4.3 and the Court's Scheduling Orders (D.E. 56, 68), Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, "Teva" or "Plaintiffs") and Defendants Amneal Pharmaceuticals of New York, LLC, Amneal Ireland Limited, Amneal Pharmaceuticals LLC, and

Amneal Pharmaceuticals, Inc. (collectively, “Amneal” or “Defendants”) hereby submit their Joint Claim Construction and Prehearing Statement (“JCCS”).

I. BACKGROUND

This Hatch-Waxman case arises out of Amneal’s submission of Abbreviated New Drug Application (“ANDA”) No. 211600 to the U.S. Food and Drug Administration seeking approval to market a generic version of ProAir® HFA (albuterol sulfate) Inhalation Aerosol (“Amneal ANDA Product”) prior to the expiration of U.S. Patent Nos. 8,132,712 (“the ’712 patent”), 9,463,289 (“the ’289 patent”), 9,808,587 (“the ’587 patent”), 10,561,808 (“the ’808 patent”), and 11,395,889 (“the ’889 patent”) (collectively, “the Patents-in-Suit”). Teva is asserting the following claims against Amneal: claims 1, 2, and 4–8 of the ’289 patent; claims 1, 2, 4–8, 11, and 12 of the ’587 patent; claims 1 and 27–29 of the ’808 patent; and claims 1–4 and 6 of the ’889 patent (collectively, “the Asserted Patents”).¹ Amneal alleges that the asserted claims are invalid and/or not infringed.

On June 10, 2024, the Court granted Amneal’s Rule 12(c) motion for judgment on the pleadings and entered an injunction ordering Teva to delist the five Patents-in-Suit from the Orange Book (D.E. 88). Teva has appealed to the United States Court of Appeals for the Federal Circuit from this Court’s Order and Opinion granting this injunction (D.E. 92).

Pursuant to Local Patent Rule 4.1, on June 5, 2024, the parties exchanged proposed terms for construction for the Asserted Patents. Pursuant to Local Patent Rules 4.2(a)-(b), on June 21, 2024, the parties exchanged preliminary claim constructions and identified intrinsic as well as extrinsic evidence in support of their preliminary claim constructions for the Asserted Patents. In accordance with Local Patent Rule 4.2(c), the parties exchanged identifications of intrinsic and

¹ On February 28, 2024, Teva provided Amneal its Disclosure of Asserted Claims Pursuant to L. Pat. R. 3.6(b) and identified no claims from the ’712 patent.

extrinsic evidence that each party intends to rely upon to oppose any other party's proposed construction on June 28, 2024. Throughout these exchanges, and continuing throughout the filing of this JCCS, the parties have met and conferred in good faith to narrow the issues and narrow the number of disputed claim terms. As reflected below, the parties have reached agreement with respect to the construction of 15 claim terms and dispute 7 additional claim terms.²

II. CONSTRUCTION OF PATENT TERMS

A. Agreed-Upon Constructions

Pursuant to Local Patent Rule 4.3(a), the parties agree to the construction of the terms set forth below for purposes of this action. Teva does not suggest or otherwise concede that these constructions would be appropriate outside the context of this litigation.

No.	Claim Term	Patent(s) / Claim(s)	Agreed-Upon Construction
1	"canister housing"	'289 patent, claim 1 '587 patent, claims 1, 12	"the portion of the inhaler body that is arranged to retain a medicament canister"
2	"inside surface"	'289 patent, claims 4, 6-8 '587 patent, claims 4, 6-8	"an interior surface"
3	"canister support formation"	'289 patent, claims 1, 4 '587 patent, claims 1, 4, 11, 12	"a formation arranged to reduce canister rocking"
4	"main surface of the inner wall"	'289 patent, claim 1 '587 patent, claims 1, 12	"inside surface of the vertical cylindrical portion of the inhaler body, where vertical means

² On June 5, 2024, Amneal originally proposed the terms "resistance force" ('808 patent, claims 27-29) and "bump surface" ('889 patent, claim 1) for construction. On June 20, 2024, the parties reached agreement that: (1) Amneal withdraws the terms "resistance force" ('808 patent, claims 27-29) and "bump surface" ('889 patent, claim 1); (2) the parties will not exchange constructions or evidence for those terms as part of these claim construction proceedings; (3) the parties will not brief indefiniteness under 35 U.S.C. § 112 at the claim construction stage; and (4) the parties agree that Amneal has preserved its indefiniteness arguments raised in its contentions for the withdrawn terms for expert discovery.

No.	Claim Term	Patent(s) / Claim(s)	Agreed-Upon Construction
			substantially parallel to the primary direction of the movement of the medicament canister when it is pressed downward by the user to expel medicament”
5	“inner wall”	’289 patent, claims 1, 4 ’587 patent, claims 1, 4, 11, 12	“an internal wall of the inhaler body, which includes a main surface of the inner wall and the inner wall through which a portion of the actuation member extends, but excludes the bottom surface, or floor, of the inhaler body”
6	“actuation member”	’289 patent, claim 1 ’587 patent, claims 1, 11, 12	“a component of the dose counter’s actuator that transmits motion from the canister to the actuator”
7	“[lying or lie] in a common plane coincident with the longitudinal axis X”	’289 patent, claim 1 ’587 patent, claims 1, 12 / claim 11	<p><u>for ’289 patent, claim 1; ’587 patent, claims 1, 12</u></p> <p>“aligned in a single plane such that a straight line can be drawn through the center of the central outlet port, the canister support formation, and the actuation member”</p> <p>/</p> <p><u>for ’587 patent, claim 11</u></p> <p>“aligned in a single plane such that a straight line can be drawn through the center of the central outlet port, the first inner wall canister support formation, the second inner wall canister support formation, and the actuation member”</p>
8	“step[(s)] formed thereon”	’289 patent, claims 5, 8 ’587 patent, claims 5, 8	“a location of changing width dimension thereon”

No.	Claim Term	Patent(s) / Claim(s)	Agreed-Upon Construction
9	“protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler”	’587 patent, claim 1	“guards against unwanted actuation by reducing rocking of the medicament canister relative to the main body of the inhaler that would otherwise be of a magnitude sufficient to move the dose counter’s actuator enough to cause unwanted incrementing (or decrementing) of the dose counter”
10	“protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member”	’587 patent, claim 12	“guards against dose count errors, including the dose counter counting a dose when the medicament canister did not fire and the dose counter not counting a dose when the medicament canister did fire, by reducing rocking of the medicament canister towards or away from the actuation member”
11	“regulator”	’808 patent, claims 1, 27 ’889 patent, claim 6	“a structure of the dose counter that modulates motion of the counter display”
12	“regulate motion of the counter display”	’808 patent, claim 1 ’889 patent, claim 6	“modulate motion of the counter display”
13	“first direction”	’808 patent, claim 1 ’889 patent, claim 6	“single direction at a time”
14	“first station”	’808 patent, claim 1 ’889 patent, claim 6	“a first region”
15	“second station”	’808 patent, claim 1 ’889 patent, claim 6	“a second region”

B. Disputed Constructions

Pursuant to Local Patent Rule 4.3(b), attached hereto as Exhibit A is a claim chart identifying the claim terms in dispute, the parties' proposed constructions, and the evidence (both intrinsic and extrinsic) that each party intends to rely on in support of its proposed construction or to oppose the other party's proposed construction. Included in the below table is a summary of the disputed claim terms, their corresponding asserted claim numbers, and the parties' proposed constructions. The parties will supplement this JCCS if they are able to reach agreement on any additional terms.

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
1	<p>"An inhaler for metered dose inhalation"</p> <p>'289 patent, claim 1</p> <p>'587 patent, claims 1, 12</p>	<p>The preamble is limiting.</p> <p>Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is:</p> <p>"An inhaler for metered dose inhalation containing an active drug capable of being dispensed via the inhaler to the lungs"</p>	<p>The phrase "An inhaler for metered dose inhalation" is part of the preamble and is not limiting. Therefore, no construction is necessary.</p> <p>To the extent the Court finds that this phrase is limiting and requires construction, this phrase should be construed as "An inhaler device for metered dose inhalation"</p>
2	<p>"medicament canister"</p> <p>'289 patent, claims 1, 2</p> <p>'587 patent, claims 1, 2, 12</p>	<p>Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is:</p> <p>"a canister containing an active drug capable of being dispensed via the inhaler to the lungs"</p>	<p>No construction necessary. Plain and ordinary meaning, i.e., "a canister for medicament"</p>
3	<p>"A dose counter for an inhaler"</p>	<p>The preamble is limiting.</p> <p>Plain and ordinary meaning in view of the claims,</p>	<p>The phrase "A dose counter for an inhaler" is part of the preamble and is not limiting.</p>

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
	'808 patent, claim 1	specification, and prosecution history, which is: "A dose counter used in connection with an inhaler"	Therefore, no construction is necessary. To the extent the Court finds that this phrase is limiting and requires construction, this phrase should be construed as "A dose counter for an inhaler device"
4	"an inhaler" '808 patent, claim 1	The preamble is limiting. Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is: "an inhaler containing an active drug capable of being dispensed via the inhaler to the lungs"	The phrase "an inhaler" is part of the preamble and is not limiting. Therefore, no construction is necessary. To the extent the Court finds that this phrase is limiting and requires construction, this phrase should be construed as "an inhaler device"
5	"An incremental dose counter for a metered dose inhaler" '889 patent, claim 1	The preamble is limiting. Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is: "An incremental dose counter used in connection with a metered dose inhaler"	The phrase "An incremental dose counter for a metered dose inhaler" is part of the preamble and is not limiting. Therefore, no construction is necessary. To the extent the Court finds that this phrase is limiting and requires construction, this phrase should be construed as "An incremental dose counter for a metered dose inhaler device"
6	"a metered dose inhaler" '889 patent, claim 1	The preamble is limiting. Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is:	The phrase "a metered dose inhaler" is part of the preamble and is not limiting. Therefore, no construction is necessary.

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
		“a metered dose inhaler containing an active drug capable of being dispensed via the inhaler to the lungs”	To the extent the Court finds that this phrase is limiting and requires construction, this phrase should be construed as “a metered dose inhaler device”
7	“canister” '889 patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is: “a canister containing an active drug capable of being dispensed via the inhaler to the lungs”	No construction necessary. Plain and ordinary meaning, i.e., “canister”

C. Claim Terms Whose Construction Will Be Most Significant to the Resolution of the Case

Pursuant to Local Patent Rule 4.3(c), the parties do not believe that the construction of any of the disputed terms will be case dispositive or substantially conducive to promoting settlement.

D. Anticipated Length of Time Necessary for the Claim Construction Hearing

Pursuant to Local Patent Rule 4.3(d), the parties anticipate and respectfully request four hours, split evenly between the sides, for the Claim Construction Hearing. To the extent the Court allocates a different amount of time for the hearing, the parties respectfully request that the allocated time be split evenly between the sides.

E. Identification of Witnesses for the Claim Construction Hearing

Pursuant to Local Patent Rule 4.3(e), the parties do not intend to call any witnesses at the Claim Construction Hearing.

Dated: July 10, 2024

/s/ Liza M. Walsh

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**EXHIBIT A – DISPUTED CONSTRUCTIONS AND EVIDENCE IDENTIFIED
UNDER LOCAL PATENT RULES 4.2(b) AND 4.2(c)**

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
1	<p>“An inhaler for metered dose inhalation”</p> <p>'289 patent, claim 1</p> <p>'587 patent, claims 1, 12</p>	<p>The preamble is limiting.</p> <p>Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is:</p> <p>“An inhaler for metered dose inhalation containing an active drug capable of being dispensed via the inhaler to the lungs”</p>	<p>The phrase “An inhaler for metered dose inhalation” is part of the preamble and is not limiting. Therefore, no construction is necessary.</p> <p>To the extent the Court finds that this phrase is limiting and requires construction, this phrase should be construed as “An inhaler device for metered dose inhalation”</p>	<p><u>The '289 patent, including:</u></p> <ul style="list-style-type: none"> • Claims 1, 2 • Abstract • 1:19-23 • 1:25-2:37, including WO 98/028033, EP-A-1486227, WO 2008/119552 • 4:30-5:13 • 5:26-58 • 6:20-58 • 7:26-35 • 7:61-8:4 • 8:27-37 • 9:12-21 • 10:47-58 • 12:13-37 • 13:10-22 • 13:40-52 • 14:25-59 • 17:4-11 • 20:14-58 • 20:62-21:8 • Fig. 7A, 10D, 21, 22 	<p>Amneal identifies the following intrinsic and extrinsic evidence in support of its construction and in opposition to Teva's construction. Amneal also may rely on the evidence that Teva has identified with respect to this claim term.</p> <p><u>Intrinsic Evidence</u></p> <p>The '289 patent generally, including at least 1:34-40, 1:49-54, 1:61-67, 2:20-25, 2:25-31, 2:31-33, Figs. 1-26, claims 1-10.</p> <p>The '587 patent generally, including at least 1:36-42, 1:51-56, 1:63-2:2, 2:22-27, 2:27-33, 2:33-35, Figs. 1-26, claims 1-22.</p> <p>The '289 and '587 file histories generally,</p>

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<p><u>The '587 patent, including:</u></p> <ul style="list-style-type: none"> • Claims 1, 2, 12, 13 • Abstract • 1:19-25 • 1:27-2:40, including WO 98/028033, EP-A-1486227, WO 2008/119552 • 4:34-5:18 • 5:31-63 • 6:24-62 • 7:30-39 • 7:65-8:8 • 8:31-40 • 9:15-24 • 10:48-58 • 12:15-39 • 13:12-24 • 13:42-54 • 14:27-61 • 17:5-11 • 20:14-58 • 20:62-21:8 • Fig. 7A, 10D, 21, 22 	<p>including at least Amendment under 37 C.F.R. § 1.116 at 1-7 (Mar. 7, 2016) (TEVAPRO_00000574 at 01575-81).</p> <p>U.S. Patent No. 10,086,156 (“the ’156 patent”) generally, including at least claim 1 (AMN_PA0058084).</p> <p><u>Extrinsic Evidence</u></p> <p><u>Webster’s Third New International Dictionary of the English Language Unabridged</u> 886 (2002) (TEVAPRO_00010935).</p> <p><u>Merriam-Webster’s Collegiate Dictionary</u> 488 (11th ed. 2007) 9TEVAPRO_00010919).</p> <p><u>The American Heritage Dictionary of the English</u></p>

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<p><u>Prosecution file history of U.S. Application No. 14/103,324, including:</u></p> <ul style="list-style-type: none"> • Original claims (Dec. 11, 2013) • Information Disclosure Statement (Dec. 11, 2013) • Information Disclosure Statement (March 10, 2014) • Information Disclosure Statement (Oct. 15, 2014) • Information Disclosure Statement (March 18, 2015) • Information Disclosure Statement (May 19, 2015) • Office action (Aug. 10, 2015) • Amendment and response (Nov. 4, 2015) • Information Disclosure Statement (April 11, 2016) <p><u>Prosecution file history of U.S. Application No. 13/110,532, including:</u></p>	<p><u>Language</u> 684-685 (5th ed. 2011) (TEVAPRO_00010912).</p> <p><u>Collins English Dictionary</u> 758 (12th ed. 2016) (TEVAPRO_00010916).</p> <p><u>Merriam-Webster's Medical Desk Dictionary</u> 226, 396, 397, 489, 503 (2005) (TEVAPRO_00010922).</p> <p><u>Merriam-Webster's Medical Dictionary</u> 218, 379, 460, 474 (2016) (TEVAPRO_00010929).</p> <p>WO 2008/119552 ("the '552 publication") generally, including at 13:24-14:6 (AMN_PA0057944).</p>

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<ul style="list-style-type: none"> Original claims (May 18, 2011) Office action (June 28, 2013) Amendment and response (September 26, 2013) <p><u>Merriam-Webster's Medical Desk Dictionary 226, 396, 397, 489, 503 (2005)</u> [TEVAPRO_00010922]</p> <p><u>Merriam-Webster's Medical Dictionary 218, 379, 460, 474 (2016)</u> [TEVAPRO_00010929]</p> <p>Additional Evidence Identified Pursuant to L. Pat. R. 4.2(c)</p> <p><u>Intrinsic Evidence</u></p> <ul style="list-style-type: none"> Evidence cited or relied upon by Teva in its June 21, 2024 identification of preliminary claim constructions and supporting evidence 	

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<p>pursuant to L. Pat. R. 4.2(a)-(b).</p> <ul style="list-style-type: none"> Evidence cited or relied upon by Defendants, including the materials cited in Defendants' June 21 and June 28, 2024 identifications of constructions and evidence pursuant to L. Pat. R. 4.2(a)-(c). Prosecution file history of U.S. Application No. 14/103,324, including: <ul style="list-style-type: none"> Final rejection (December 7, 2015) Amendment and response (March 7, 2016) Notice of allowance/allowability (May 20, 2016) <p><u>Extrinsic Evidence</u></p> <ul style="list-style-type: none"> Evidence cited or relied upon by Teva in its June 21, 2024 identification of preliminary claim 	

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<p>constructions and supporting evidence pursuant to L. Pat. R. 4.2(a)-(b).</p> <ul style="list-style-type: none"> • Evidence cited or relied upon by Defendants, including the materials cited in Defendants' June 21 and June 28, 2024 identifications of constructions and evidence pursuant to L. Pat. R. 4.2(a)-(c). • Defendants' Noninfringement Contentions, including materials cited. • Defendants' Invalidity Contentions, including materials cited. • Defendants' Notice Letter. • Defendants' Interrogatory Responses. • Expert opinions and/or testimony regarding how a person of ordinary skill in the art would 	

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.	
2	<p>"medicament canister"</p> <p>'289 patent, claims 1, 2</p> <p>'587 patent, claims 1, 2, 12</p>	<p>Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is:</p> <p>"a canister containing an active drug capable of being dispensed via the inhaler to the lungs"</p>	<p>No construction necessary.</p> <p>Plain and ordinary meaning, i.e., "a canister for medicament"</p>	<p><u>The '289 patent, including:</u></p> <ul style="list-style-type: none"> • Claims 1, 2 • Abstract • 1:19-23 • 1:25-2:37, including WO 98/028033, EP-A-1486227, WO 2008/119552 • 4:30-5:13 • 5:26-58 • 6:20-58 • 7:26-35 • 7:61-8:4 • 8:27-37 • 9:12-21 • 10:47-58 • 12:13-37 • 13:10-22 • 13:40-52 • 14:25-59 	<p>Amneal identifies the following intrinsic and extrinsic evidence in support of its construction and in opposition to Teva's construction. Amneal also may rely on the evidence that Teva has identified with respect to this claim term.</p> <p><u>Intrinsic Evidence</u></p> <p>The '289 patent generally, including at least 1:27-31, 4:46-65, 5:26-34, 6:20-23, 6:34-43, 6:50-58, 9:12-21, Figs. 1-26, claims 1 and 2.</p> <p>The '587 patent generally, including at least 1:29-33, 4:51-5:3, 5:31-39, 6:24-27,</p>

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<ul style="list-style-type: none"> • 17:4-11 • 20:14-58 • 20:62-21:8 • Fig. 7A, 10D, 21, 22 <p><u>The '587 patent, including:</u></p> <ul style="list-style-type: none"> • Claims 1, 2, 12, 13, 14, 21 • Abstract • 1:21-25 • 1:27-2:40, including WO 98/028033, EP-A-1486227, WO 2008/119552 • 4:34-5:18 • 5:31-63 • 6:24-62 • 7:30-39 • 7:65-8:8 • 8:31-40 • 9:15-24 • 10:48-58 • 12:15-39 • 13:12-24 • 13:42-54 • 14:27-61 • 17:5-12 • 20:14-58 	<p>6:38-47, 6:54-62, 9:15:24, Figs. 1-26, claims 1, 2, 12, 13, 14, and 21.</p> <p>The '156 patent generally, including at least claim 1 (AMN_PA0058084).</p> <p><u>Extrinsic Evidence</u> <u>Merriam-Webster's Medical Desk Dictionary</u> 226, 396, 397, 489, 503 (2005) (TEVAPRO_00010922).</p> <p><u>Merriam-Webster's Medical Dictionary</u> 218, 379, 460, 474 (2016) (TEVAPRO_00010929).</p> <p>The '552 publication generally, including at 13:24-14:6 (AMN_PA0057944).</p>

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<ul style="list-style-type: none"> • 20:62-21:8 • Fig. 7A, 10D, 21, 22 <p><u>Prosecution file history of U.S. Application No. 14/103,324, including:</u></p> <ul style="list-style-type: none"> • Original claims (Dec. 11, 2013) • Information Disclosure Statement (Dec. 11, 2013) • Information Disclosure Statement (March 10, 2014) • Information Disclosure Statement (Oct. 15, 2014) • Information Disclosure Statement (March 18, 2015) • Information Disclosure Statement (May 19, 2015) • Office action (Aug. 10, 2015) • Amendment and response (Nov. 4, 2015) • Information Disclosure Statement (April 11, 2016) 	

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<p><u>Prosecution file history of U.S. Application No. 13/110,532, including:</u></p> <ul style="list-style-type: none"> • Original claims (May 18, 2011) • Office action (June 28, 2013) • Amendment and response (September 26, 2013) <p><u>Merriam-Webster's Medical Desk Dictionary 226, 396, 397, 489, 503 (2005)</u> <u>[TEVAPRO_00010922]</u></p> <p><u>Merriam-Webster's Medical Dictionary 218, 379, 460, 474 (2016)</u> <u>[TEVAPRO_00010929]</u></p> <p>Additional Evidence Identified Pursuant to L. Pat. R. 4.2(c)</p> <p><u>Intrinsic Evidence</u></p> <ul style="list-style-type: none"> • Evidence cited or relied upon by Teva in its June 21, 2024 identification of 	

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<p>preliminary claim constructions and supporting evidence pursuant to L. Pat. R. 4.2(a)-(b).</p> <ul style="list-style-type: none"> • Evidence cited or relied upon by Defendants, including the materials cited in Defendants' June 21 and June 28, 2024 identifications of constructions and evidence pursuant to L. Pat. R. 4.2(a)-(c). • Prosecution file history of U.S. Application No. 14/103,324, including: <ul style="list-style-type: none"> • Final rejection (December 7, 2015) • Amendment and response (March 7, 2016) • Notice of allowance/allowability (May 20, 2016) 	

				<u>Extrinsic Evidence</u> <ul style="list-style-type: none">• Evidence cited or relied upon by Teva in its June 21, 2024 identification of preliminary claim constructions and supporting evidence pursuant to L. Pat. R. 4.2(a)-(b).• Evidence cited or relied upon by Defendants, including the materials cited in Defendants' June 21 and June 28, 2024 identifications of constructions and evidence pursuant to L. Pat. R. 4.2(a)-(c).• Defendants' Noninfringement Contentions, including materials cited.• Defendants' Invalidity Contentions, including materials cited.• Defendants' Notice Letter.• Defendants' Interrogatory Responses.• Expert opinions and/or testimony regarding how a person of ordinary skill in the art would	
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No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.	
3	<p>"A dose counter for an inhaler"</p> <p>'808 patent, claim 1</p>	<p>The preamble is limiting.</p> <p>Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is:</p> <p>"A dose counter used in connection with an inhaler"</p>	<p>The phrase "A dose counter for an inhaler" is part of the preamble and is not limiting. Therefore, no construction is necessary.</p> <p>To the extent the Court finds that this phrase is limiting and requires construction, this phrase should be construed as "A dose counter for an inhaler device"</p>	<p><u>The '808 patent, including:</u></p> <ul style="list-style-type: none"> • Claim 1 • Abstract • 1:23-27 • 1:31-2:40 • 2:44-53 • 4:1-6 • 4:26-5:3 • 7:30-39 • 8:57-9:3 • 9:38-10:27 • Figs. 1-26 <p><u>Prosecution file history of U.S. Application No. 15/262,818, including:</u></p> <ul style="list-style-type: none"> • Original claims (Sep. 12, 2016) 	<p>Amneal identifies the following intrinsic and extrinsic evidence in support of its construction and in opposition to Teva's construction. Amneal also may rely on the evidence that Teva has identified with respect to this claim term.</p> <p><u>Intrinsic Evidence</u></p> <p>The '808 patent generally, including at least 1:38-44, 1:53-58, 1:65-2:4, 2:23-28, 2:28-34, 2:34-36, Figs. 1-26, claims 1-29.</p> <p>The '808 file history generally, including at least Response to Office Action</p>

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<p><u>Webster's Third New International Dictionary of the English Language Unabridged 886 (2002)</u> [TEVAPRO_00010935]</p> <p><u>Merriam-Webster's Collegiate Dictionary 488 (11th ed. 2007)</u> [TEVAPRO_00010919]</p> <p><u>The American Heritage Dictionary of the English Language 684-685 (5th ed. 2011)</u> [TEVAPRO_00010912]</p> <p><u>Collins English Dictionary 758 (12th ed. 2016)</u> [TEVAPRO_00010916]</p> <p><u>Merriam-Webster's Medical Desk Dictionary 226, 396, 397, 489, 503 (2005)</u> [TEVAPRO_00010922]</p> <p><u>Merriam-Webster's Medical Dictionary 218, 379, 460, 474</u></p>	<p>at 1-9 (Mar. 15, 2017) (TEVAPRO_00001907 at 02033-41).</p> <p>The '156 patent generally, including at least claim 1 (AMN_PA0058084).</p> <p><u>Extrinsic Evidence</u> <u>Webster's Third New International Dictionary of the English Language Unabridged 886 (2002)</u> (TEVAPRO_00010935).</p> <p><u>Merriam-Webster's Collegiate Dictionary 488 (11th ed. 2007)</u> 9TEVAPRO_00010919).</p> <p><u>The American Heritage Dictionary of the English Language 684-685 (5th ed. 2011)</u> (TEVAPRO_00010912).</p>

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<p>(2016) <u>[TEVAPRO_00010929]</u></p> <p>Additional Evidence Identified Pursuant to L. Pat. R. 4.2(c)</p> <p><u>Intrinsic Evidence</u></p> <ul style="list-style-type: none"> Evidence cited or relied upon by Teva in its June 21, 2024 identification of preliminary claim constructions and supporting evidence pursuant to L. Pat. R. 4.2(a)-(b). Evidence cited or relied upon by Defendants, including the materials cited in Defendants' June 21 and June 28, 2024 identifications of constructions and evidence pursuant to L. Pat. R. 4.2(a)-(c). Prosecution file history of U.S. Application No. 15/262,818, including: 	<p><u>Collins English Dictionary</u> 758 (12th ed. 2016) (TEVAPRO_00010916).</p> <p><u>Merriam-Webster's Medical Desk Dictionary</u> 226, 396, 397, 489, 503 (2005) (TEVAPRO_00010922).</p> <p><u>Merriam-Webster's Medical Dictionary</u> 218, 379, 460, 474 (2016) (TEVAPRO_00010929).</p> <p>The '552 publication generally, including at 13:24-14:6 (AMN_PA0057944).</p>

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<ul style="list-style-type: none"> • Original claims (Sep. 12, 2016) • Non-final rejection (December 16, 2016) • Amendment and response (March 15, 2017) • Office action (July 19, 2017) • Reply to office action (Oct. 17, 2017) • Advisory action before the filing of an appeal brief (Oct. 25, 2017) • Appellant's brief (May 21, 2018) • Examiner's answer to appeal brief (Aug. 7, 2018) • Reply brief (Oct. 4, 2018) • Patent board decision (Sep. 20, 2019) • Notice of allowance/allowability (October 2, 2019) 	

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<u>Extrinsic Evidence</u> <ul style="list-style-type: none">• Evidence cited or relied upon by Teva in its June 21, 2024 identification of preliminary claim constructions and supporting evidence pursuant to L. Pat. R. 4.2(a)-(b).• Evidence cited or relied upon by Defendants, including the materials cited in Defendants' June 21 and June 28, 2024 identifications of constructions and evidence pursuant to L. Pat. R. 4.2(a)-(c).• Defendants' Noninfringement Contentions, including materials cited.• Defendants' Invalidity Contentions, including materials cited.• Defendants' Notice Letter.	

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<ul style="list-style-type: none"> Defendants' Interrogatory Responses. Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence. 	
4	<p>"an inhaler"</p> <p>'808 patent, claim 1</p>	<p>The preamble is limiting.</p> <p>Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is:</p> <p>"an inhaler containing an active drug capable of being dispensed via the inhaler to the lungs"</p>	<p>The phrase "an inhaler" is part of the preamble and is not limiting. Therefore, no construction is necessary.</p> <p>To the extent the Court finds that this phrase is limiting and requires construction, this phrase should be construed as "an inhaler device"</p>	<p><u>The '808 patent, including:</u></p> <ul style="list-style-type: none"> Claims 1, 2 Abstract 1:23-27 1:29-2:40, including WO 98/028033, EP-A-1486227, WO 2008/119552 4:34-5:19 5:31-63 6:24-62 7:30-39 7:65-8:8 8:31-41 	<p>Amneal identifies the following intrinsic and extrinsic evidence in support of its construction and in opposition to Teva's construction. Amneal also may rely on the evidence that Teva has identified with respect to this claim term.</p> <p><u>Intrinsic Evidence</u></p> <p>The '808 patent generally, including at least 1:38-44,</p>

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<ul style="list-style-type: none"> • 9:15-24 • 10:48-58 • 12:15-39 • 13:12-24 • 13:42-54 • 14:27-61 • 17:5-12 • 20:14-58 • 20:62-21:8 • Fig. 7A, 10D, 21, 22 <p><u>Prosecution file history of U.S. Application No. 14/103,324, including:</u></p> <ul style="list-style-type: none"> • Original claims (Dec. 11, 2013) • Information Disclosure Statement (Dec. 11, 2013) • Information Disclosure Statement (March 10, 2014) • Information Disclosure Statement (Oct. 15, 2014) • Information Disclosure Statement (March 18, 2015) • Information Disclosure Statement (May 19, 2015) 	<p>1:53-58, 1:65-2:4, 2:23-28, 2:28-34, 2:34-36, Figs. 1-26, claims 1-29.</p> <p>The '808 file history generally, including at least Response to Office Action at 1-9 (Mar. 15, 2017) (TEVAPRO_00001907 at -02033-41).</p> <p>The '156 patent generally, including at least claim 1 (AMN_PA0058084).</p> <p><u>Extrinsic Evidence</u> <u>Merriam-Webster's Medical Desk Dictionary</u> 226, 396, 397, 489, 503 (2005) (TEVAPRO_00010922).</p> <p><u>Merriam-Webster's Medical Dictionary</u> 218, 379, 460, 474 (2016) (TEVAPRO_00010929).</p>

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<ul style="list-style-type: none"> • Office action (Aug. 10, 2015) • Amendment and response (Nov. 4, 2015) • Information Disclosure Statement (April 11, 2016) <p><u>Prosecution file history of U.S. Application No. 13/110,532, including:</u></p> <ul style="list-style-type: none"> • Original claims (May 18, 2011) • Office action (June 28, 2013) • Amendment and response (September 26, 2013) <p><u>Merriam-Webster's Medical Desk Dictionary 226, 396, 397, 489, 503 (2005)</u> <u>[TEVAPRO_00010922]</u></p> <p><u>Merriam-Webster's Medical Dictionary 218, 379, 460, 474 (2016)</u> <u>[TEVAPRO_00010929]</u></p>	<p>The '552 publication generally, including at 13:24-14:6 (AMN_PA0057944).</p>

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<p>Additional Evidence Identified Pursuant to L. Pat. R. 4.2(c)</p> <p><u>Intrinsic Evidence</u></p> <ul style="list-style-type: none"> • Evidence cited or relied upon by Teva in its June 21, 2024 identification of preliminary claim constructions and supporting evidence pursuant to L. Pat. R. 4.2(a)-(b). • Evidence cited or relied upon by Defendants, including the materials cited in Defendants' June 21 and June 28, 2024 identifications of constructions and evidence pursuant to L. Pat. R. 4.2(a)-(c). • Prosecution file history of U.S. Application No. 15/262,818, including: <ul style="list-style-type: none"> • Original claims (Sep. 12, 2016) 	

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<ul style="list-style-type: none"> • Non-final rejection (December 16, 2016) • Amendment and response (March 15, 2017) • Information Disclosure Statement (May 30, 2017) • Office action (July 19, 2017) • Reply to office action (Oct. 17, 2017) • Advisory Action Before the Filing of an Appeal Brief (Oct. 25, 2017) • Appellant's brief (May 21, 2018) • Examiner's answer to appeal brief (Aug. 7, 2018) • Reply brief (Oct. 4, 2018) • Patent board decision (Sep. 20, 2019) • Notice of allowance/allowability (October 2, 2019) 	

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<u>Extrinsic Evidence</u> <ul style="list-style-type: none"> • Evidence cited or relied upon by Teva in its June 21, 2024 identification of preliminary claim constructions and supporting evidence pursuant to L. Pat. R. 4.2(a)-(b). • Evidence cited or relied upon by Defendants, including the materials cited in Defendants' June 21 and June 28, 2024 identifications of constructions and evidence pursuant to L. Pat. R. 4.2(a)-(c). • Defendants' Noninfringement Contentions, including materials cited. • Defendants' Invalidity Contentions, including materials cited. • Defendants' Notice Letter. 	

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<ul style="list-style-type: none"> Defendants' Interrogatory Responses. Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence. 	
5	<p>"An incremental dose counter for a metered dose inhaler"</p> <p>'889 patent, claim 1</p>	<p>The preamble is limiting.</p> <p>Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is:</p> <p>"An incremental dose counter used in connection with a metered dose inhaler"</p>	<p>The phrase "An incremental dose counter for a metered dose inhaler" is part of the preamble and is not limiting. Therefore, no construction is necessary.</p> <p>To the extent the Court finds that this phrase is limiting and requires construction, this phrase</p>	<p><u>The '889 patent, including:</u></p> <ul style="list-style-type: none"> Claim 1 Abstract 1:23-27 1:31-2:40 2:44-53 4:1-6 4:26-5:3 7:30-39 8:57-9:3 9:38-10:27 Figs. 1-26 	<p>Amneal identifies the following intrinsic and extrinsic evidence in support of its construction and in opposition to Teva's construction. Amneal also may rely on the evidence that Teva has identified with respect to this claim term.</p> <p><u>Intrinsic Evidence</u> The '889 patent generally, including at least 1:38-44,</p>

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
			should be construed as "An incremental dose counter for a metered dose inhaler device"	<p><u>Prosecution file history of U.S. Application No. 16/915,558, including:</u></p> <ul style="list-style-type: none"> Original claims (June 29, 2020) <p><u>Webster's Third New International Dictionary of the English Language Unabridged 886 (2002) [TEVAPRO_00010935]</u></p> <p><u>Merriam-Webster's Collegiate Dictionary 488 (11th ed. 2007) [TEVAPRO_00010919]</u></p> <p><u>The American Heritage Dictionary of the English Language 684-685 (5th ed. 2011) [TEVAPRO_00010912]</u></p> <p><u>Collins English Dictionary 758 (12th ed. 2016) [TEVAPRO_00010916]</u></p> <p><u>Merriam-Webster's Medical Desk Dictionary 226, 396,</u></p>	<p>1:53-58, 1:65-2:4, 2:23-28, 2:28-34, 2:34-36, Figs. 1-26, claims 1-6.</p> <p>The '889 file history generally, including at least Amendment under 37 C.F.R. § 1.111 at 1-6 (Oct. 21, 2021) (TEVAPRO_00006442 at 06619-24).</p> <p>The '156 patent generally, including at least claim 1 (AMN_PA0058084).</p> <p><u>Extrinsic Evidence</u> <u>Webster's Third New International Dictionary of the English Language Unabridged 886 (2002) (TEVAPRO_00010935).</u></p> <p><u>Merriam-Webster's Collegiate Dictionary 488 (11th ed. 2007) 9TEVAPRO_00010919).</u></p>

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<p>397, 489, 503 (2005) <u>[TEVAPRO_00010922]</u></p> <p><u>Merriam-Webster's Medical Dictionary</u> 218, 379, 460, 474 (2016) <u>[TEVAPRO_00010929]</u></p> <p>Additional Evidence Identified Pursuant to L. Pat. R. 4.2(c)</p> <p><u>Intrinsic Evidence</u></p> <ul style="list-style-type: none"> Evidence cited or relied upon by Teva in its June 21, 2024 identification of preliminary claim constructions and supporting evidence pursuant to L. Pat. R. 4.2(a)-(b). Evidence cited or relied upon by Defendants, including the materials cited in Defendants' June 21 and June 28, 2024 identifications of constructions and 	<p><u>The American Heritage Dictionary of the English Language</u> 684-685 (5th ed. 2011) (TEVAPRO_00010912).</p> <p><u>Collins English Dictionary</u> 758 (12th ed. 2016) (TEVAPRO_00010916).</p> <p><u>Merriam-Webster's Medical Desk Dictionary</u> 226, 396, 397, 489, 503 (2005) (TEVAPRO_00010922).</p> <p><u>Merriam-Webster's Medical Dictionary</u> 218, 379, 460, 474 (2016) (TEVAPRO_00010929).</p> <p>The '552 publication generally, including at 13:24-14:6 (AMN_PA0057944).</p>

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<p>evidence pursuant to L. Pat. R. 4.2(a)-(c).</p> <ul style="list-style-type: none"> • Prosecution file history of U.S. Application No. 16/915,558, including: <ul style="list-style-type: none"> • Non-final rejection (April 21, 2021) • Amendment and response (Oct. 21, 2021) • Final rejection (November 3, 2021) • Amendment and response (April 4, 2022) • Notice of allowance/allowability (April 15, 2022) <p><u>Extrinsic Evidence</u></p> <ul style="list-style-type: none"> • Evidence cited or relied upon by Teva in its June 21, 2024 identification of preliminary claim constructions and supporting evidence pursuant to L. Pat. R. 4.2(a)-(b). 	

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<ul style="list-style-type: none"> • Evidence cited or relied upon by Defendants, including the materials cited in Defendants' June 21 and June 28, 2024 identifications of constructions and evidence pursuant to L. Pat. R. 4.2(a)-(c). • Defendants' Noninfringement Contentions, including materials cited. • Defendants' Invalidity Contentions, including materials cited. • Defendants' Notice Letter. • Defendants' Interrogatory Responses • Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other 	

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				intrinsic evidence, and the parties' extrinsic evidence.	
6	<p>"a metered dose inhaler"</p> <p>'889 patent, claim 1</p>	<p>The preamble is limiting.</p> <p>Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is:</p> <p>"a metered dose inhaler containing an active drug capable of being dispensed via the inhaler to the lungs"</p>	<p>The phrase "a metered dose inhaler" is part of the preamble and is not limiting. Therefore, no construction is necessary.</p> <p>To the extent the Court finds that this phrase is limiting and requires construction, this phrase should be construed as "a metered dose inhaler device"</p>	<p><u>The '889 patent, including:</u></p> <ul style="list-style-type: none"> • Claims 1, 2 • Abstract • 1:23-27 • 1:29-2:40, including WO 98/028033, EP-A-1486227, WO 2008/119552 • 4:34-5:19 • 5:31-63 • 6:24-62 • 7:30-39 • 7:65-8:8 • 8:31-41 • 9:15-24 • 10:48-58 • 12:15-39 • 13:12-24 • 13:42-54 • 14:27-61 • 17:5-12 • 20:14-58 • 20:62-21:8 	<p>Amneal identifies the following intrinsic and extrinsic evidence in support of its construction and in opposition to Teva's construction. Amneal also may rely on the evidence that Teva has identified with respect to this claim term.</p> <p><u>Intrinsic Evidence</u></p> <p>The '889 patent generally, including at least 1:38-44, 1:53-58, 1:65-2:4, 2:23-28, 2:28-34, 2:34-36, Figs. 1-26, claims 1-6.</p> <p>The '889 file history generally, including at least Amendment under 37 C.F.R. § 1.111 at 1-6 (Oct. 21, 2021)</p>

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<ul style="list-style-type: none"> Fig. 7A, 10D, 21, 22 <p><u>Prosecution file history of U.S. Application No. 14/103,324, including:</u></p> <ul style="list-style-type: none"> Original claims (Dec. 11, 2013) Information Disclosure Statement (Dec. 11, 2013) Information Disclosure Statement (March 10, 2014) Information Disclosure Statement (Oct. 15, 2014) Information Disclosure Statement (March 18, 2015) Information Disclosure Statement (May 19, 2015) Office action (Aug. 10, 2015) Amendment and response (Nov. 4, 2015) Information Disclosure Statement (April 11, 2016) 	<p>(TEVAPRO_00006442 at -06619-24).</p> <p>The '156 patent generally, including at least claim 1 (AMN_PA0058084).</p> <p><u>Extrinsic Evidence</u> <u>Merriam-Webster's Medical Desk Dictionary</u> 226, 396, 397, 489, 503 (2005) (TEVAPRO_00010922).</p> <p><u>Merriam-Webster's Medical Dictionary</u> 218, 379, 460, 474 (2016) (TEVAPRO_00010929).</p> <p>The '552 publication generally, including at 13:24-14:6 (AMN_PA0057944).</p>

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<p><u>Prosecution file history of U.S. Application No. 13/110,532, including:</u></p> <ul style="list-style-type: none"> • Original claims (May 18, 2011) • Office action (June 28, 2013) • Amendment and response (September 26, 2013) <p><u>Merriam-Webster's Medical Desk Dictionary 226, 396, 397, 489, 503 (2005)</u> <u>[TEVAPRO_00010922]</u></p> <p><u>Merriam-Webster's Medical Dictionary 218, 379, 460, 474 (2016)</u> <u>[TEVAPRO_00010929]</u></p> <p>Additional Evidence Identified Pursuant to L. Pat. R. 4.2(c)</p> <p><u>Intrinsic Evidence</u></p> <ul style="list-style-type: none"> • Evidence cited or relied upon by Teva in its June 21, 2024 identification of 	

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<pre> preliminary claim constructions and supporting evidence pursuant to L. Pat. R. 4.2(a)-(b). • Evidence cited or relied upon by Defendants, including the materials cited in Defendants' June 21 and June 28, 2024 identifications of constructions and evidence pursuant to L. Pat. R. 4.2(a)-(c). • Prosecution file history of U.S. Application No. 16/915,558, including: • Original claims (June 29, 2020) • Information disclosure statement (June 29, 2020) • Non-final rejection (April 21, 2021) • Amendment and response (Oct. 21, 2021) </pre>	

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<ul style="list-style-type: none"> • Final rejection (November 3, 2021) • Information disclosure statement (December 10, 2021) • Amendment and response (April 4, 2022) • Notice of allowance/allowability (April 15, 2022) <p><u>Extrinsic Evidence</u></p> <ul style="list-style-type: none"> • Evidence cited or relied upon by Teva in its June 21, 2024 identification of preliminary claim constructions and supporting evidence pursuant to L. Pat. R. 4.2(a)-(b). • Evidence cited or relied upon by Defendants, including the materials cited in Defendants' June 21 and June 28, 2024 identifications of constructions and 	

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<p>evidence pursuant to L. Pat. R. 4.2(a)-(c).</p> <ul style="list-style-type: none"> • Defendants' Noninfringement Contentions, including materials cited. • Defendants' Invalidity Contentions, including materials cited. • Defendants' Notice Letter. • Defendants' Interrogatory Responses • Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence. 	
7	"canister"	Plain and ordinary meaning in view of the claims, specification,	No construction necessary.	<p><u>The '889 patent, including:</u></p> <ul style="list-style-type: none"> • Claims 1, 2 • Abstract 	Amneal identifies the following intrinsic and extrinsic evidence in

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
	'889 patent, claim 1	and prosecution history, which is: “a canister containing an active drug capable of being dispensed via the inhaler to the lungs”	Plain and ordinary meaning, i.e., “canister”	<ul style="list-style-type: none"> • 1:23-27 • 1:29-2:40, including WO 98/028033, EP-A-1486227, WO 2008/119552 • 4:34-5:18 • 5:31-63 • 6:24-62 • 7:30-39 • 7:65-8:8 • 8:31-41 • 9:15-24 • 10:48-58 • 12:15-39 • 13:12-24 • 13:42-54 • 14:27-61 • 17:5-11 • 20:14-58 • 20:62-21:8 • Fig. 7A, 10D, 21, 22 <p><u>Prosecution file history of U.S. Application No. 14/103,324, including:</u></p> <ul style="list-style-type: none"> • Original claims (Dec. 11, 2013) 	<p>support of its construction and in opposition to Teva's construction. Amneal also may rely on the evidence that Teva has identified with respect to this claim term.</p> <p><u>Intrinsic Evidence</u> The '889 patent generally, including at least 1:31-35, 4:39-50, 4:51-5:3, 5:4-18, 5:31-39, 6:24-27, 6:38-47, 6:54-62, 9:15-24, 12:19-39, 13:55-14:10, 14:11-15, Figs. 1-26, claim 1.</p> <p>The '156 patent generally, including at least claim 1 (AMN_PA0058084).</p> <p><u>Extrinsic Evidence</u> <u>Merriam-Webster's Medical Desk Dictionary</u> 226, 396, 397, 489, 503 (2005) (TEVAPRO_00010922).</p>

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<ul style="list-style-type: none"> • Information Disclosure Statement (Dec. 11, 2013) • Information Disclosure Statement (March 10, 2014) • Information Disclosure Statement (Oct. 15, 2014) • Information Disclosure Statement (March 18, 2015) • Information Disclosure Statement (May 19, 2015) • Office action (Aug. 10, 2015) • Amendment and response (Nov. 4, 2015) • Information Disclosure Statement (April 11, 2016) <p><u>Prosecution file history of U.S. Application No. 13/110,532, including:</u></p> <ul style="list-style-type: none"> • Original claims (May 18, 2011) • Office action (June 28, 2013) 	<p><u>Merriam-Webster's Medical Dictionary</u> 218, 379, 460, 474 (2016) (TEVAPRO_00010929).</p> <p>The '552 publication generally, including at 13:24-14:6 (AMN_PA0057944).</p>

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<ul style="list-style-type: none"> Amendment and response (September 26, 2013) <p><u>Merriam-Webster's Medical Desk Dictionary 226, 396, 397, 489, 503 (2005)</u> [TEVAPRO_00010922]</p> <p><u>Merriam-Webster's Medical Dictionary 218, 379, 460, 474 (2016)</u> [TEVAPRO_00010929]</p> <p>Additional Evidence Identified Pursuant to L. Pat. R. 4.2(c)</p> <p><u>Intrinsic Evidence</u></p> <ul style="list-style-type: none"> Evidence cited or relied upon by Teva in its June 21, 2024 identification of preliminary claim constructions and supporting evidence pursuant to L. Pat. R. 4.2(a)-(b). Evidence cited or relied upon by Defendants, 	

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<p>including the materials cited in Defendants' June 21 and June 28, 2024 identifications of constructions and evidence pursuant to L. Pat. R. 4.2(a)-(c).</p> <ul style="list-style-type: none"> • Prosecution file history of U.S. Application No. 16/915,558, including: <ul style="list-style-type: none"> • Original claims (June 29, 2020) • Information disclosure statement (June 29, 2020) • Non-final rejection (April 21, 2021) • Amendment and response (Oct. 21, 2021) • Final rejection (November 3, 2021) • Information disclosure statement (December 10, 2021) • Amendment and response (April 4, 2022) 	

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<ul style="list-style-type: none"> • Notice of allowance/allowability (April 15, 2022) <p><u>Extrinsic Evidence</u></p> <ul style="list-style-type: none"> • Evidence cited or relied upon by Teva in its June 21, 2024 identification of preliminary claim constructions and supporting evidence pursuant to L. Pat. R. 4.2(a)-(b). • Evidence cited or relied upon by Defendants, including the materials cited in Defendants' June 21 and June 28, 2024 identifications of constructions and evidence pursuant to L. Pat. R. 4.2(a)-(c). • Defendants' Noninfringement Contentions, including materials cited. 	

No.	Claim Term Patent(s) / Claim(s)	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Plaintiffs' Evidence	Defendants' Evidence
				<ul style="list-style-type: none">• Defendants' Invalidity Contentions, including materials cited.• Defendants' Notice Letter.• Defendants' Interrogatory Responses.• Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.	